DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed August 21, 2009. Claims 1, 6-8, 10-12 and 14-20 are pending, with claims 1, 6-8, 10 and 11 examined. Because this Office Action sets forth new rejections that are not necessitated by amendment, this Office Action is made NON-FINAL. Any rejection of record that is not present has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al (US 6,821,512) in view of Hateboer et al (WO 00/63403, cited by applicants). This rejection has been made again since the language of the wherein clause of claim 1 and claims 10 and 11is functional and therefore is not being given any patentable weight.

Gao et al (columns 1-2, 7 and 10) teach a PER.C6 cell transfected with a vector encoding an IgA molecule. The IgA molecule can be a human IgA. However, they do not teach the IgA molecule integrated into the cell's genome. Gao et al are also silent about whether the IgA molecule is amplified in the cell. Since there is no teaching in

Gao about amplifying the molecule, it is assumed, absent evidence to the contrary, that that the IgA molecule is not amplified in the cell.

Hateboer et al taught a method of producing recombinant proteins in human cells, with particular regards to the field of monoclonal antibody production (pg 1, lines 1-8). Hateboer et al contemplate the use of PER.C6 cells, deposited at the ECACC under #96022940 (pg 7, line 20), to express humanized antibodies (pgs 11-20), and disclose that the PER.C6 cells may express one or more nucleic acids encoding a heavy chain, a variable heavy chain, a light chain and/or a variable light chain of an immunoglobulin, or a functional derivative, homologue and/or fragment thereof (pg 18, lines 4-8). One type of antibody disclosed is to the EPCAM antigen (page 14). Hateboer et al disclose a working example wherein the PER.C6 cells express humanized monoclonal antibodies (pgs 57-67). Per.C6 cells are immortal cells, and in Ex. 7, the cells are grown for 4-5 weeks. It is assumed that they maintain expression of E1A and E1B, since it is the E1 genes that confer immortality. Applicants also teach in their specification in Ex. 2 that Per.C6 cells were cultured for up to 3 weeks, however, they do discuss expression of E1A or E1B. However, since Per.C6 cells contain E1A and E1B, and the cells are intact and viable, it is assumed that E1A and E1B are expressed in this instance like in the Hateboer reference.

It would have been obvious to one of ordinary skill in the art to integrate the IgA molecule, because Hateboer et al teach that integration can lead to stability for expression and production. An artisan would be motivated to produce IgA in PER.C6 cells because Hateboer et al suggest that PER.C6 cells are advantageous for having

been documented extensively, behaving significantly better in the process of upscaling, suspension growth and growth factor independence, e.g. bioreactor growth to very high densities suitable for large scale production. PER.C6 cells have the additional advantage that they can be cultured in the absence of animal- or human-derived serum or serum components. Thus, isolation of the artisan-desired protein is easier, while the safety is enhanced due to the absence of additional proteins (pg 7, lines 20-37 of Hateboer et al).

Furthermore, because most commercially attractive proteins are human, it is advantageous to use a human cell to produce said protein, because human cells, e.g. PER.C6, would have the advantage of post-translationally modifying, e.g. glycosylating, the immunoglobulin as per the human physiology, wherein the presence of carbohydrates can be critical for antigen clearance functions and antibody activity. PER.C6 cells are advantageous for providing reliable and consistent glycosylation patterns on an antibody by removing the cell type variable and having simplified cell culture conditions that can negatively impact antibody glycosylation patterns (pg 5, lines 9-17; pg 15, lines 20 of Hateboer et al).

Response to Arguments

Applicants have argued that the 35 U.S.C. 103(a) rejection is improper due to the priority claims of 09/549,463, now U.S. 6,855,544, and 60/129,452, however, there is no support for a cell comprising a recombinant nucleic acid encoding an IgA molecule in

either reference. Therefore, Applicants are awarded the filing date of July 18, 2002 as their priority date.

Allowable Subject Matter

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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